



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/716,169	12/17/96	ANDERTON	961125

18M1/0722
WEBB ZIESENHEIM BRUENING LOGSDON
ORKIN & HANSON
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH PA 15219-1818

EXAMINER
NOLAN, P

ART UNIT
1816

PAPER NUMBER

DATE MAILED: 07/22/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/716,169Applicant(s)
Anderton et al.Examiner
Patrick J. NolanGroup Art Unit
1816☐ Responsive to communication(s) filed on _____☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-20 is/are pending in the application.Of the above, claim(s) 9-16, 19, and 20 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-8, 17, and 18 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☒ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152☒ **SEQUENCE LETTER**

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. This application is a 371 of PCT/NL95/00108.
2. Claims 1-20 are pending.
3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant's attention is directed to the figures, tables and specification, wherein amino acid sequences that are longer than 4 amino acids in length do not have corresponding SEQ ID NO.'s.

Restriction/Election

3. Restriction is required under 35 U.S.C. 121 and 372.
4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, 17 and 18, drawn to a peptide and compositions of such peptide.

Group II, claim 9, drawn to a method of making a peptide.

Group III, claims 10-12 and 19, drawn to a nucleotide sequence and its expression.

Group IV, claims 13 and 20, drawn to a T cell or T cell receptor..

Group V, claims 14-16, drawn to an antibody and compositions of such antibody.

5. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The protein as claimed in group

I was publicly disclosed prior to Applicant's invention in the Journal of Immunology, Volume 141: 2749-2754 in October of 1988.

6. During a telephone conversation with Barbara E .Johnson on 7/2/97 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 and 17-18. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9-16 and 19-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

8. Claims designated as claims 1-21 have been renumbered as claims 1-20, respectively, in accordance with 37 CFR 1.126. Claim 7 was provisionally deleted by Applicant, so originally filed claims 8-21 were renumbered to claims 7-20. If any more claims are added, they should start with claim 21. To avoid confusion, reference should be made to renumbered claim numbers in the future because they are the official claim numbers. Accordingly, claims 1-20 are pending in the application.

112:2nd

9. Claims 1-8 and 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "sequence identity". How is identity measured? Clarification is required.

Claim 7 is indefinite because claim 6 recites a limitation of a peptide comprising at least 5 amino acids which are identical, while claim 7 which depends on claim 6 recites a peptide which epitopes contain less than 4 consecutive amino acids which are identical. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Oftung et al. (AS).

Oftung et al., teach a microbial peptide, peptide 91-105 of *M. tuberculosis*, which is identical at 5 amino acids to the mammalian stress homologue, (Table I, in particular) (i.e. peptide 91-95 of *M. tuberculosis* is identical to 116-120 of the human stress homologue). Oftung et al., also teach the use of the peptide in an assay, (i.e. a composition) to determine cellular proliferation, (page 2750, 1st column, in particular). A composition is a composition regardless of its intended use.

The prior art teachings anticipate the claimed invention.

11. Claims 1-4 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent 262,710 (AL).

The '710 patent teaches a peptide, Antigen A, (i.e. hsp65 of *M. bovis* BCG, which Applicant recites is identical to hsp65 of *M. tuberculosis*), wherein amino acid sequence 171-240 has 5 consecutive amino acids that are identical to the human stress homologue, (i.e. peptide 171-175 of hsp65 of *M. bovis* BCG is identical to peptide 197-201 of the human stress protein) (page 7, in particular). The '710 patent also teaches the use of the peptide in diagnostic as well as pharmaceutical compositions (page 7, lines 38-44, in particular).

The prior art teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office

Art Unit: 1816

action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 8 is rejected under 35 U.S.C. § 103 as being unpatentable over Oftung et al., (AS), or European Patent 262,710 (AL) in view of U.S. Patent 5,643,873 (A).

Oftung et al., and the '710 patent have been discussed supra. The claimed invention differs from the prior art teachings only by the recitation of a peptide mimetic of the naturally occurring peptide.

However, the '873 patent teaches that peptide mimetics are art recognized as useful for having the same or similar biological activity as the native peptide but with more favorable activity than the peptide with respect to solubility, stability, and susceptibility to hydrolysis and proteolysis (column 19, lines 15-30, in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute peptide mimetics taught by the '873 patent with the

Art Unit: 1816

native peptides taught by the '710 patent or by Oftung et al., with the expectation that peptide mimetics increase bioactivity through decreased susceptibility to proteolysis as taught by the '873 patent.

13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

15. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1816, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick Nolan, Ph.D.

July 17, 1997



FRANK C. EISENSCHENK
PRIMARY EXAMINER
GROUP 1800

7/17/97